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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,724	12/08/2003	Antonius Arnoldus Christiaan Jacobs	I 1999.452 US CI	5481
31846	7590	02/22/2006	EXAMINER KAUSHAL, SUMESH	
INTERVET INC. PATENT DEPARTMENT PO BOX 318 MILLSBORO, DE 19966-0318			ART UNIT 1633	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,724

Applicant(s)

JACOBS ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 11/28/05 has been acknowledged.

Claims 1-5 are canceled.

Claims 6-11 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Double Patenting

Claims 6-11 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,682,745 for the same reasons of record as set forth in the office action mailed on 06/28/05. Claims 6-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,120,775 (ref. of record), for the same reasons of record as set forth in the office action mailed on 06/28/05. In addition the scope of live bacterial vaccine as claimed encompasses live attenuated bacterial vaccine as claimed in '745 and 775.

Response to Arguments

Regarding the double patenting issues above, the applicant requested the rejection be held in abeyance until allowable subject matter is identified, therefore the rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 6-11 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for protecting a mammal against *Streptococcus equi* infection by administering a live attenuated *Streptococcus equi* strain (TW980), does not reasonably provide enablement for a method for protecting a mammal against all bacterial infection by administering any and all live bacterial vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the same reasons of record as set forth in the office action mailed on 06/28/05.

Response to arguments

The applicant arguments regarding enablement issue on pages 14-16 of response filed on 11/28/05 has been fully considered. The applicant argues that instant claims have been amended to recite live bacterial vaccine instead of live attenuated bacterial vaccine. The applicant argues that the specification provides three examples illustrating inventions using four bacterial strains and two mammalian host species.

However, applicant's arguments are found not persuasive because the only disclosed utility of the invention as claimed is the bacterial vaccination to prevent bacterial infection (spec. page 1). In addition given the broadest reasonable interpretation the scope of instant invention as claimed encompasses live bacterial vaccines that are attenuated. Besides TW 928 (*Streptococcus equi*) the instant specification fails to disclose any live bacterial vaccine which one skilled in the art would consider as live bacterial vaccine. Furthermore the scope of invention as claimed encompasses a submucosal injection various live bacterial strains like *Actinobacillus equuli*, *A. pleuropneumoniae*, *Actinomyces pyogenes*, *Botdetella bronchiseptica*, *Brucella abortus*, *Clostridium perfringens*, *Corynebacterium bovis*, *C pseudotuberculosis*, *Erysipelotrix rhusiopathiae*, *Escherichia coli*, *Haemophilus parasuis*, *Leptospira canicola*, *L. hardjo*, *L. icterohaemorrhagiae*, *L. poriona*, *Mycobacterium bovis*, *Mycoplasma bovis*, *M. hyopneumoniae*, *Noccatdia asteroides*, *Pasteurella haemolytica*, *P. multocida*, *Pseudomonas mallei*,

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Rhodococcus equi, *Salmonella choleraesuis*, *S. dublin*, *S. typhimurium*, *Serpulina hyodysenteriae*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *St. pneumoniae*, *St. suis*, or *St. uberis*, wherein the only disclosed utility of such method is to provide vaccination against these strains. At best the instant specification only discloses the use of *Streptococcus equi* attenuated strains (TW 928 and TW928/sls), which are deletion mutant vaccine strains (spec. page 7, example-1). Besides TW 928 (*Streptococcus equi*), the instant specification fails to disclose any live bacterial vaccine. At best the specification discloses that submucosal injection of live *S. zooepidemicus* and *A. pyogenes* in horses and cows respectively resulted in smaller size of abscesses as compared to intermuscular injection. The earlier office action provided clear evidence that the development of vaccine and its outcome after administration is considered highly unpredictable (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002, Tiball et al Vaccine 19:4175-4184, 2001 ref. of record.). The state of the art clearly teaches that understanding of regulatory pathways that affect bacterial virulence and protective antigens that provides long-term immune protection are considered germane to the development of a live attenuated bacterial vaccine. Besides inducing a smaller size of oral abscess, the specification fails to provide any evidence that these animals are protected from any subsequent infections upon a challenge.

It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), *Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. In instant case considering the disclosed utility of instant method as claimed it is unclear how one skilled in the art would use the instant invention especially in context of bacterial infection. Therefore it would require an undue amount of experimentation to administer a live

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bacterial strain selected from the above-mentioned bacterial strains and its efficacy as a vaccine to prevent infection. Furthermore invention as claimed is not merely the administration of a bacterial strain because the only disclosed utility of the claimed method is protection of mammal from a bacterial infection. MPEP clearly states that office is to give claims their broadest reasonable interpretation in light of the supporting disclosure. See *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) and MPEP 2100. Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill. The earlier office action clearly provided the evidence that a rational approach to design a bacterial vaccine involves genetic modification of the bacterial pathogen to make the pathogen less virulent while maintaining the stability of protective antigen expression that provides immune protection.

In addition, sub mucosal injection of any live bacterial strain (virulent) as vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and vaccination outcome base upon the immune protection the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir,1988). The amount of undue experimentation required would include sub mucosal injection of any live bacterial strains (as claimed) and evaluation of vaccine efficacy in order to provide immune protection. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

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Conclusion

No claims are allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**


SUMESH KAUSHAL
PRIMARY EXAMINER
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